As Introduced

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H. B. No. 1004

Representatives Bird, John

To amend sections 4723.4812 and 4729.284; to enact section 4729.286; and to repeal section 4731.90 of the Revised Code to revise the law governing pharmacist dispensing of nicotine replacement therapy and to authorize pharmacists to dispense oral contraceptive therapy pursuant to protocols developed by the State Board of Pharmacy.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF OHIO:

Section 1. That sections 4723.4812 and 4729.284 be amended and section 4729.286 of the Revised Code be enacted to read as follows:

Sec. 4723.4812. (A) ~~A certified nurse-midwife, clinical nurse specialist, or certified nurse practitioner who has established a protocol that meets the requirements of section 4729.284 of the Revised Code and the rules adopted under that section may authorize one or more pharmacists to use the protocol for the purpose of dispensing nicotine replacement therapy under section 4729.284 of the Revised Code.~~

~~(B)~~ The board of nursing shall adopt rules establishing standards and procedures to be followed by a certified nurse-midwife, clinical nurse specialist, or certified nurse

practitioner when prescribing a drug that may be administered by a pharmacist pursuant to section 4729.45 of the Revised Code. The rules shall be adopted in accordance with Chapter 119. of the Revised Code and in consultation with the state board of pharmacy.

~~(C)~~ (B) A certified nurse-midwife, clinical nurse specialist or certified nurse practitioner who has established a protocol that meets the requirements specified by the state board of pharmacy in rules adopted under section 4729.47 of the Revised Code may authorize one or more pharmacists and any of the pharmacy interns supervised by the pharmacist or pharmacists to use the protocol for the purpose of dispensing epinephrine under section 4729.47 of the Revised Code.

Sec. 4729.284. (A) As used in this section, "nicotine replacement therapy" means ~~a drug, including~~ a ~~dangerous~~ drug~~,~~ that ~~delivers small doses of nicotine to an individual~~ is approved for the purpose of aiding in tobacco cessation or smoking cessation.

(B) The state board of pharmacy shall establish a statewide protocol in accordance with rules adopted under division (G) of this section. Following the protocol's establishment, the board may authorize one or more pharmacists to use the protocol for the purpose of dispensing nicotine replacement therapy.

(C) Subject to division ~~(C)~~ (D) of this section, if use of ~~a~~ the protocol that has been developed under this section has been authorized under division (B) of this section ~~4723.4812 or 4731.90 of the Revised Code~~, a pharmacist may dispense nicotine replacement therapy without a prescription in accordance with that protocol to individuals who are eighteen years old or older

and seeking to quit using tobacco-containing products.

~~(C)~~ (D) For a pharmacist to be authorized to dispense nicotine replacement therapy under this section, the pharmacist shall do both of the following:

(1) Successfully complete a course on nicotine replacement therapy that is taught by a provider that is accredited by the accreditation council for pharmacy education, or another provider approved by the state board of pharmacy, and that meets requirements established in rules adopted under this section;

(2) Practice in accordance with ~~a~~ the protocol that ~~meets the requirements of division (D) of~~ is established under this section.

~~(D) All of the following apply with respect to the protocol required by this section:~~

~~(1) The protocol shall be established by a physician authorized under Chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery or a certified nurse-midwife, clinical nurse specialist, or certified nurse practitioner licensed under Chapter 4723. of the Revised Code.~~

~~(2) The protocol shall specify a definitive set of treatment guidelines and the locations at which a pharmacist may dispense nicotine replacement therapy under this section.~~

~~(3) The protocol shall include provisions for implementation of the following requirements:~~

~~(a) Use by the pharmacist of a screening procedure, recommended by the United States centers for disease control and prevention or another organization approved by the board, to~~

~~determine if an individual is a good candidate to receive nicotine replacement therapy dispensed as authorized by this section;~~

~~(b) A requirement that the pharmacist refer high-risk individuals or individuals with contraindications to a primary care provider or, as appropriate, to another type of provider;~~

~~(c) A requirement that the pharmacist develop and implement a follow-up care plan in accordance with guidelines specified in rules adopted under this section, including a recommendation by the pharmacist that the individual seek additional assistance with behavior change, including assistance from the Ohio tobacco quit line made available by the department of health.~~

~~(4) The protocol shall satisfy any additional requirements established in rules adopted under this section.~~

~~(E)(1) Documentation related to screening, dispensing, and follow-up care plans shall be maintained in the records of the pharmacy where the pharmacist practices for at least three years. Dispensing of nicotine replacement therapy may be documented on a prescription form, and the form may be assigned a number for recordkeeping purposes.~~

~~(2) Not later than seventy-two hours after a screening is conducted under this section, the pharmacist shall provide notice to the individual's primary care provider, if known, or to the individual if the primary care provider is unknown. The notice shall include results of the screening, and if applicable, the dispensing record and follow-up care plan.~~

~~A copy of the documentation identified in division (E)(1) of this section shall also be provided to the individual or the~~

~~individual's primary care provider on request.~~

~~(F)~~ (E) This section does not affect the authority of a pharmacist to do any of the following:

(1) Fill or refill prescriptions for ~~nicotine replacement therapy~~drugs approved for the purpose of aiding in tobacco cessation or smoking cessation, which may include prescriptions for such drugs available over-the-counter;

(2) Sell ~~nicotine replacement therapy that does not require a prescription~~over-the-counter drugs approved for the purpose of aiding in tobacco cessation or smoking cessation.

~~(G)~~ (F) No pharmacist shall do either of the following:

(1) Dispense nicotine replacement therapy in accordance with a protocol unless the requirements of division ~~(C)~~ (D) of this section have been met;

(2) Delegate to any person the pharmacist's authority to engage in or supervise the dispensing of nicotine replacement therapy.

~~(H)(1)~~ (G) The board shall adopt rules to implement this section. The rules shall be adopted in accordance with Chapter 119. of the Revised Code and shall include all of the following:

~~(a)~~ (1) Provisions specifying the nicotine replacement therapy that may be dispensed in accordance with ~~a~~ the protocol established pursuant to this section;

~~(b)~~ (2) Requirements for courses on nicotine replacement therapy, including requirements that are consistent with any standards established for such courses by the United States centers for disease control and prevention;

~~(c)~~ (3) Requirements for protocols to be followed by pharmacists in dispensing nicotine replacement therapy~~;~~

~~(d) Guidelines for follow-up care plans~~, including screening, treatment, referral, notice, documentation, and recordkeeping requirements.

~~(2) Prior to adopting rules regarding requirements for protocols to be followed by pharmacists in dispensing of nicotine replacement therapy, the state board of pharmacy shall consult with the state medical board, board of nursing, and department of health.~~

~~(I)~~ (H) All of the following procedures apply to the establishment of a statewide protocol in accordance with rules adopted under division (G) of this section:

(1) Before the protocol is finalized, the state board of pharmacy shall submit a draft protocol to the state medical board for review.

(2) During the sixty-day period immediately following receipt of the draft protocol, the state medical board may submit comments to the state board of pharmacy. Any comments from the state medical board shall be submitted in writing.

(3) If no comments are submitted by the state medical board, the state board of pharmacy shall proceed with finalizing the protocol.

(4) If comments are submitted by the state medical board, the state board of pharmacy shall review the comments. If it determines that revisions will not be made to incorporate or otherwise address the comments, the state board of pharmacy shall submit to the state medical board an explanation of the reasons for not making the revisions. Thereafter, the state

board of pharmacy shall proceed with finalizing the protocol.

(5) To finalize the protocol, a copy shall be delivered to the president of the state board of pharmacy for the president's signature. Once the president has signed the protocol, the protocol is finalized and remains in effect until any revisions are made under division (I) of this section.

(I) The state board of pharmacy shall review the protocol established in accordance with rules adopted under division (G) of this section every two years and shall make revisions as the board considers necessary. If the board considers revisions to be necessary, the board shall make the revisions by following the same procedures described in division (H) of this section for establishing the protocol.

(J) The state board of pharmacy, through electronic communication, shall inform all individuals licensed by the board when the initial protocol and any revised protocol are finalized. The board shall maintain on its internet web site a copy of the version of the protocol that is in effect.

(K) The state board of pharmacy and state medical board are not liable in damages in a civil action for injury, death, or loss to person or property allegedly arising from the use of a protocol established in accordance with rules adopted under division (G) of this section, unless an act or omission by the applicable board in developing, commenting on, revising, or finalizing the protocol constitutes willful or wanton misconduct.

~~A physician, certified nurse-midwife, clinical nurse specialist, or certified nurse practitioner who in good faith authorizes a pharmacist to dispense nicotine replacement therapy~~

~~in accordance with a protocol developed pursuant to rules adopted under division (H) of this section is not liable for or subject to any of the following for any action or omission of the individual to whom the nicotine replacement therapy is dispensed: damages in any civil action, prosecution in any criminal proceeding, or professional disciplinary action.~~

Sec. 4729.286. (A) As used in this section, "oral contraceptive therapy" means a drug that is approved to prevent pregnancy.

(B) The state board of pharmacy shall establish a statewide protocol in accordance with rules adopted under division (G) of this section. Following the protocol's establishment, the board may authorize one or more pharmacists to use the protocol for the purpose of dispensing oral contraceptive therapy.

(C) Subject to division (D) of this section, if use of the protocol that has been developed under this section has been authorized under division (B) of this section, a pharmacist may dispense oral contraceptive therapy without a prescription in accordance with that protocol to individuals who are eighteen years old or older.

(D) For a pharmacist to be authorized to dispense oral contraceptive therapy under this section, the pharmacist shall do both of the following:

(1) Successfully complete a course on oral contraceptive therapy that is taught by a provider that is accredited by the accreditation council for pharmacy education, or another provider approved by the state board of pharmacy, and that meets requirements established in rules adopted under this section;

(2) Practice in accordance with the protocol that is established under this section.

(E) This section does not affect the authority of a pharmacist to do any of the following:

(1) Fill or refill prescriptions for oral contraceptive drugs, which may include prescriptions for oral contraceptive drugs also available over-the-counter;

(2) Sell over-the-counter oral contraceptive drugs.

(F) No pharmacist shall do either of the following:

(1) Dispense oral contraceptive therapy in accordance with a protocol unless the requirements of division (D) of this section have been met;

(2) Delegate to any person the pharmacist's authority to engage in or supervise the dispensing of oral contraceptive therapy.

(G) The board shall adopt rules to implement this section. The rules shall be adopted in accordance with Chapter 119. of the Revised Code and shall include all of the following:

(1) Provisions specifying the oral contraceptive therapies that may be dispensed in accordance with the protocol established pursuant to this section;

(2) Requirements for courses on oral contraceptive therapy, including requirements that are consistent with any standards established for such courses by the United States centers for disease control and prevention;

(3) Requirements for protocols to be followed by pharmacists in dispensing oral contraceptive therapy, including

screening, treatment, referral, notice, documentation, and recordkeeping requirements.

(H) All of the following procedures apply to the establishment of a statewide protocol in accordance with rules adopted under division (G) of this section:

(1) Before the protocol is finalized, the state board of pharmacy shall submit a draft protocol to the state medical board for review.

(2) During the sixty-day period immediately following receipt of the draft protocol, the state medical board may submit comments to the state board of pharmacy. Any comments from the state medical board shall be submitted in writing.

(3) If no comments are submitted by the state medical board, the state board of pharmacy shall proceed with finalizing the protocol.

(4) If comments are submitted by the state medical board, the state board of pharmacy shall review the comments. If it determines that revisions will not be made to incorporate or otherwise address the comments, the state board of pharmacy shall submit to the state medical board an explanation of the reasons for not making the revisions. Thereafter, the state board of pharmacy shall proceed with finalizing the protocol.

(5) To finalize the protocol, a copy shall be delivered to the president of the state board of pharmacy for the president's signature. Once the president has signed the protocol, the protocol is finalized and remains in effect until any revisions are made under division (I) of this section.

(I) The state board of pharmacy shall review the protocol established in accordance with rules adopted under division (G)

of this section every two years and shall make revisions as the board considers necessary. If the board considers revisions to be necessary, the board shall make the revisions by following the same procedures that are described in division (H) of this section for establishing the protocol.

(J) The state board of pharmacy, through electronic communication, shall inform all individuals licensed by the board when the initial protocol and any revised protocol are finalized. The board shall maintain on its internet web site a copy of the version of the protocol that is in effect.

(K) The state board of pharmacy and state medical board are not liable in damages in a civil action for injury, death, or loss to person or property allegedly arising from the use of a protocol established in accordance with rules adopted under division (G) of this section, unless an act or omission by the applicable board in developing, commenting on, revising, or finalizing the protocol constitutes willful or wanton misconduct.

(L) Nothing in this section shall be construed to authorize a pharmacist to dispense an abortifacient.

Section 2. That existing sections 4723.4812 and 4729.284 of the Revised Code are hereby repealed.

Section 3. That section 4731.90 of the Revised Code is hereby repealed.